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Biotechnology in Italy - Annual 2013

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Report Highlights:
Again, this year, Italy's biotechnology industry is characterized as a dynamic and promising sector, despite the difficult economic situation that biotech companies have to confront on a daily basis. Italy has a large and profitable biotech industry operating in the medical, industrial, and agricultural sector, ranking 3rd in Europe in the number of pure biotech companies.

Overview

Table 1: Italian Biotech Industry main figures

	2012	2013
Number of companies	412	407
Total turnover (€mln)	6.7	7.1
R&D Investments (€mln)	1.8	1.8
Number of employees in R&D	6,748	6,739

Source: Assobiotec report 2013

Again, this year, Italy's biotechnology industry is characterized as a dynamic and promising sector, despite the difficult economic situation that biotech companies have to confront on a daily basis. The number of biotech companies in Italy has sharply increased over the last decade. At the end of 2012, 407 biotech companies engaged in research and development were recorded. Among these, 256 fall under the definition of pure biotech companies (whose core business activities are exclusively related to biotechnology), ranking third in Europe just behind Germany and the United Kingdom.

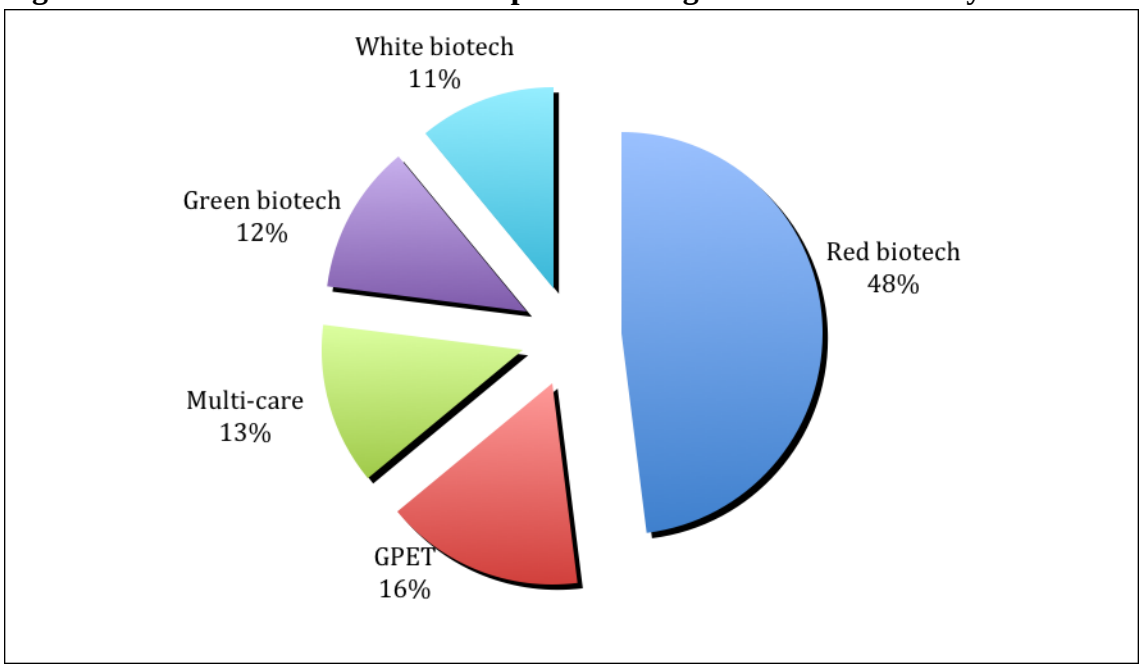
Biotechnology companies can be divided into the following categories according to their field of operation:

- Red Biotech: medical biotechnology
- Green Biotech: agricultural biotechnology
- White Biotech: industrial biotechnology
- Genomics, proteomics and enabling technologies (GPET)
- Multi-core: mix of the previous categories.

Forty-eight percent of the 407 recorded companies are exclusively active in red biotech, 16 percent in Genomics, Proteomics and Enabling Technologies (GPET), 12 percent in green biotech, 11 percent in white biotech, while 13 percent operate in more than one field of application as multi-core.

Per Figure 2 below, approximately 75 percent of the Italian biotech companies are micro-sized or small (less than 50 employees); 13 percent are medium-sized companies (from 50 to 250 employees), and the remaining 12 percent are large-sized ones (more than 250 employees). The large entities are mainly pharmaceutical companies, accounting for 79 percent of total turnover.

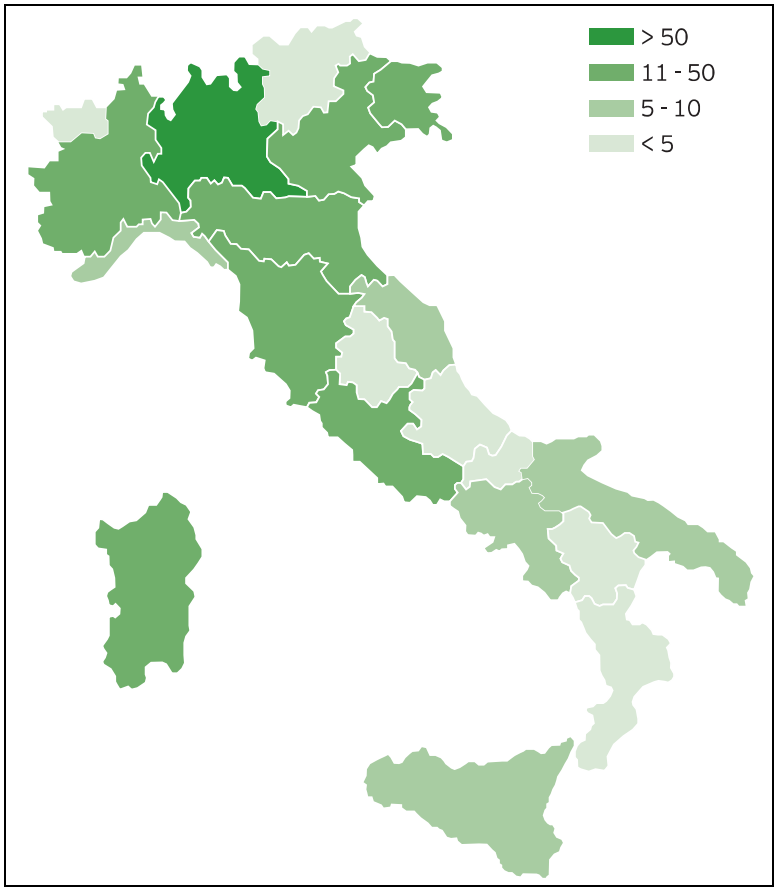
Figure 2: Distribution of biotech companies among the 5 sectors in Italy



Source: Assobiotec report 2013

Most biotech companies are concentrated in the Center-North of Italy (see Figure 3 below) in Lombardy (31 percent), Piedmont (11.5 percent), Tuscany (9.3 percent), Latium (9 percent), Emilia-Romagna (9 percent), Veneto (5.8 percent), and Friuli Venezia Giulia (5 percent). Lombardy has been particularly praised for its university infrastructure, strong tradition of entrepreneurship, and its regional government's support for biotech companies. As to their location, most work within science parks or incubators (46 percent), others have independent headquarters (37 percent), while the remainder are located near universities, clinical centers, or research institutes (17 percent).

Figure 3: Geographical distribution – number of biotech companies



Source: Assobiotec Report 2013

A) RED BIOTECH (MEDICAL BIOTECHNOLOGY)

Table 4: Italian Red Biotech Industry main figures

	2012	2013
Number of companies	245	235
Total turnover (€mln)	6.4	6.7
R&D Investments (€mln)	1.6	1.7
Number of employees in R&D	5,478	5,436

Source: Assobiotec report 2013

Red biotech accounts for 95 percent of total turnover of the whole biotech industry, representing 94 percent of total investments.

Red biotech activities can be categorized as follows:

Therapeutic: development of drugs and other therapeutic approaches, such as gene- or cell-based therapies for the treatment of various diseases;

Vaccines: biological preparations for prophylaxis and treatment;

Drug delivery: technologies to convey the drugs to a specific site through optimization of their absorption and distribution (advanced materials, liposomes, antibodies, cell therapy, etc.);

Molecular diagnostics: DNA/RNA-based tests for the diagnosis, prognosis, and detection of any predispositions to specific diseases and for the analysis of pathogenic mechanisms;

Drug discovery: synthesis, optimization, and characterization of drug candidates; assay development, screening, and validation activities on medicinal products.

Currently, 235 enterprises are active in red biotech: the majority of biotechnology companies are dedicated exclusively to human health (84 percent), while the remainder consist of multi-core companies (16 percent). Most of the latter are active in GPET, which also includes nanobiotechnology, confirming the fact that companies tend to manage their ancillary activities internally. As regards their origin, 38 percent of the companies that operate in the red biotech field derive from start-ups, 20 percent from subsidiaries of multinational companies, 18 percent from academic spin-offs, 7 percent from Italian pharmaceuticals, and 8 percent from industrial spin-offs or spin-outs.

B) WHITE BIOTECH (INDUSTRIAL BIOTECHNOLOGY)

Table 5: Italian White Biotech industry main figures

	2012	2013
Number of companies	61	62
Total turnover (€mln)	174	276
R&D Investments (€mln)	30	29
Number of employees in R&D	493	505

Source: Assobiotec report 2013

The industrial white biotech refers to the use of modern biotech methods for the processing and the production of chemicals, materials, and fuels, including "bioremediation" technologies for environmental protection. Currently, 62 companies deal with industrial biotech, 41 specifically dedicated to white biotech, and 21 multi-cores. The majority of white companies (87 percent) are micro-sized or small with 49 percent of the white companies originating from start-ups, 26 percent from academic spin-offs, and 7 percent from industrial spin-offs or spin-outs. Almost all the white biotech

turnover can be attributed to pure Italian biotech companies. Total revenues reached €174 million, representing a € 13 million increase compared to 2011— but this increase can be attributed to the growth in revenues from a single pure biotech company of medium size.

C) GREEN BIOTECH (AGRICULTURAL BIOTECHNOLOGY)

Table 6: Italian Green Biotech industry main figures

	2012	2013
Number of companies	85	85
Total turnover (€mln)	109	110
R&D Investments (€mln)	115	112
Number of employees in R&D	777	798

Source: Assobiotec report 2013

The green biotech category includes the use of modern biotech methods for the production of transgenic plants with applications in the food, chemical, material or fuel sector, molecular pharming (production of drugs in plants), and testing to reveal the presence of ingredients/contaminants in food. The majority of companies (74 percent) operating in the green biotech sector are made up of pure biotech, while the remainder (26 percent) are divided among other Italian biotech (22 percent) and Italian subsidiaries of multinational companies (4 percent). In terms of size, the predominant presence of small (18 percent) and micro (68 percent) companies, followed by medium (8 percent) and large organizations (6 percent), characterize the green sector. Testing represents a relevant share of green biotech.

Below is a short list of applications that biotechnology provides to the agro-food sector in Italy:

Identification of a pathogen genotype in food: the use of DNA-based tests allows for distinguishing different bacterium varieties (i.e. Salmonella, Listeria, and Escherichia coli) and identifying the pathology source;

Analysis of food allergens: the use of advanced DNA-based technologies (PCR) allows for identifying food allergens much more easily than using traditional methods;

GMO Identification: the analysis to investigate the presence of GMO products through biotechnology has become a wide spread standard procedure, as a result of EC Regulation N.1830/2003, concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

D) GENOMICS, PROTEOMICS AND ENABLING TECHNOLOGIES (GPET)

Genomics, proteomics, and enabling technologies (GPET) include all genomic (investigation of the

structure and function of genes) and proteomic activities (analysis of protein regulation, expression, structure, post-transitional modification, interactions and function), bioinformatics, biochips and other bio-related tools, biopharmaceutical production, molecular basic research, and further enabling technologies.